

## § 10.90

submit only one copy. Comments will be considered in determining whether further modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or §10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994; 65 FR 56477, Sept. 19, 2000]

## § 10.90 Food and Drug Administration regulations, recommendations, and agreements.

(a) *Regulations.* FDA regulations are issued in the FEDERAL REGISTER under §10.40 or §10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions that will be enforced as legal requirements, or which are intended only as guidance documents and recommendations, or both. The dissemination of draft notices and regulations is subject to §10.80.

(b) [Reserved]

(c) *Recommendations.* In addition to the guidance documents subject to §10.115, FDA often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model State and local ordinances, or personnel practices for reducing radiation exposure, issued under 42 U.S.C. 243 and 21 U.S.C. 360ii. These recommendations may, in the discretion of the Commissioner, be handled under the procedures established in §10.115, except that the recommendations will be included in a separate public file of recommenda-

## 21 CFR Ch. I (4–1–10 Edition)

tions established by the Division of Dockets Management and will be separated from the guidance documents in the notice of availability published in the FEDERAL REGISTER, or be published in the FEDERAL REGISTER as regulations under paragraph (a) of this section.

(d) *Agreements.* Formal agreements, memoranda of understanding, or other similar written documents executed by FDA and another person will be included in the public file on agreements established by the Freedom of Information Staff (HFI-35) under §20.108. A document not included in the public file is deemed to be rescinded and has no force or effect whatever.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 65 FR 56477, Sept. 19, 2000; 75 FR 16346, Apr. 1, 2010]

## § 10.95 Participation in outside standard-setting activities.

(a) *General.* This section applies to participation by FDA employees in standard-setting activities outside the agency. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal Government agencies.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Freedom of Information Staff.

(3) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitations will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.